

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CRIMINAL ACTION NO. 00-10023-GAO

UNITED STATES OF AMERICA,

v.

THOMAS RONALD THEODORE,
Defendant.

OPINION AND ORDER

November 13, 2009

O'TOOLE, D.J.

I. Background

Following his conviction on a twelve-count indictment, the defendant Thomas Ronald Theodore moved for a new trial on the ground that he had been denied the effective assistance of counsel. See Strickland v. Washington, 466 U.S. 668 (1984). After hearing argument on the motion but without conducting an evidentiary hearing, Judge Lindsay, who had presided over the trial, denied the motion. On appeal, the First Circuit concluded that an evidentiary hearing should have been held on the new trial motion and remanded the matter for that purpose.¹ The court noted that “facts adduced at the hearing may lend some support to Theodore’s claim that he was constructively abandoned by his counsel throughout trial. See United States v. Cronin, 466 U.S. 648, 659, 104 S.Ct. 2039, 80 L.Ed.2d 657 (1984).” United States v. Theodore, 354 F.3d 1, 7 (1st Cir. 2003). The court added:

¹ The court of appeals otherwise rejected Theodore’s claims on appeal directed at the conduct of the trial itself.

We caution, however, that prejudice may be presumed only in three narrowly circumscribed situations: “First, a trial is presumptively unfair if the accused is completely denied the presence of counsel at a critical stage of the proceedings. Second, such a presumption is warranted if counsel entirely fails to subject the prosecution's case to meaningful adversarial testing. Third, prejudice may be presumed in the presence of circumstances under which a competent lawyer would likely not be able to render effective assistance.” Ouber v. Guarino, 293 F.3d 19, 33 (1st Cir. 2002) (internal citations and quotation marks omitted).

Id. at 7 n.1.

Judge Lindsay recused himself on remand, and the case was redrawn to Judge Tauro, who conducted a two-day evidentiary hearing at which both Judge Lindsay and Theodore’s trial counsel, John Noonan, testified. Judge Tauro found that Noonan’s trial performance had clearly fallen “below an objective standard of reasonableness, easily satisfying the first part of the Strickland analysis.” United States v. Theodore, 345 F. Supp. 2d 123, 129 (D. Mass. 2004).

The second part of the test is whether the deficient performance of counsel may have adversely affected the outcome of the trial. See Strickland, 466 U.S. at 692. Judge Tauro concluded that prejudice to Theodore could be presumed under one of the conditions identified in Cronic, namely, that by reason of Noonan’s poor work, “the prosecution’s case has ‘never been subjected to the crucible of meaningful adversarial testing.’” Theodore, 345 F. Supp. 2d at 129 (quoting Alabama v. Shelton, 535 U.S. 654, 667 (2002)). Judge Tauro found that “Noonan’s representation of Theodore, overall, failed to subject the government’s case to meaningful adversarial testing.” Id. at 130. He therefore concluded that prejudice to Theodore was to be presumed and granted the motion for a new trial.

The government appealed, arguing that Judge Tauro had erred in presuming prejudice under Cronic.² The First Circuit agreed. United States v. Theodore, 468 F.3d 52, 57 (1st Cir. 2006). The court vacated the grant of a new trial and again remanded the case for consideration of whether Theodore had demonstrated actual prejudice under Strickland. Id. at 58.

The remanded case was then assigned to me. The parties have submitted extensive briefs and have been heard in oral argument. I have carefully reviewed the transcripts of the trial, including pre- and post-trial motion hearings, as well as the transcript of the evidentiary hearing held before Judge Tauro. Theodore has proffered as an addendum to his brief, and I have reviewed and considered, some additional materials that are not found in the trial record. Theodore has also requested an additional evidentiary hearing, but I conclude that, in light of his proffer and related argument, it is not necessary to take more evidence. The request for an evidentiary hearing is therefore denied.

II. The Prosecution's Case

Theodore was indicted and convicted on nine counts of mail fraud and three counts of violating the Food, Drug and Cosmetic Act (“FDCA”). The evidence supporting the convictions is set forth in the prior published opinions in this case, and it is necessary here only to refer to as much of the evidence as pertains to Theodore’s arguments on the present motion.

The nub of the prosecution’s case was that Theodore falsely claimed that Private Biologicals Corporation (“PBC”), the company he formed with Thomas Rodgers, had developed a proprietary process for generating a product he called LK-200, which he claimed had success in treating patients with advanced forms of cancer. The claims that the process and product were “proprietary” were crucial both to potential scientific and medical allies and to potential

² The government conceded that Noonan’s performance had been objectively deficient under the first part of the Strickland test.

investors. Thus described, LK-200 appealed to scientists because it was said to be novel and to investors because it was said to be unique, and therefore valuable. The trial evidence was overwhelming that LK-200 was neither novel nor unique but simply a commonly known byproduct (a “supernatant”) generated by a well-known process of putting a line of human cells, in this case lymphoid B blood cells, into a centrifuge.

The claim to have a proprietary process and/or product was not only the core of the scheme to defraud, it was also the claim most clearly demonstrated to have been false. Moreover, it was not the only fraudulent claim; it was supported by other false or misleading claims.

There was evidence that Theodore falsely asserted that part of the process of manufacturing LK-200 occurred outside the United States, specifically in the Bahamas where there was a clinic at which LK-200 was actually administered to cancer patients, some of whom traveled from the United States to get the injections. That part of the manufacturing process for LK-200 was done offshore was an important fact if true because it meant that PBC did not need to comply with the FDCA; a product manufactured outside the United States could be shipped to purchasers within the country free of federal regulation. Specifically, Theodore’s claim was that supernatant generated at PBC’s Woburn, Massachusetts, facility was “activated” in the Bahamas by additional processing. In fact, the uncontradicted evidence was that the only “activation” that occurred was that LK-200 generated in Woburn and frozen for shipment by air freight to the Bahamas was thawed out at the Bahamian clinic before being injected into a patient. Theodore’s claim aside, there was no evidence that any change to the physical, chemical, or biological composition of LK-200 was performed in the Bahamas.

There was also uncontradicted evidence that some LK-200 was shipped directly from Woburn to destinations within the United States. Such shipments violated federal law. To

disguise the violation, the evidence indicated, Theodore instructed that the packages display an address for the sender that falsely indicated that the packages had originated in the Bahamas, so that they would appear to be compliant with the law. Nine such falsely labeled packages sent via Federal Express were the mailings specifically alleged in each of the mail fraud counts.

In addition, Theodore typically added the initials “M.D.” after his name in communicating with people, and he referred to himself—and sought to have others to address him—as “Dr. Theodore.” This self-identification was more a misleading partial truth than an outright falsity. His claim to the degree and the honorific title was grounded in a diploma he had received from a medical school in the Dominican Republic in 1980. He had apparently qualified for the degree by passing an examination; there was no evidence he actually attended the Dominican school. However, in the mid-1980’s he had his Massachusetts professional license revoked when the board of registration discovered he had misrepresented his academic career in applying for the license. He was subsequently charged with, and he pled guilty to, one count of mail fraud in this Court in 1987. That conviction, and the guilty plea colloquy that preceded it, were in evidence.³

In short, the government’s case was very strong. Whatever nibbling at its corners might have been possible, at its core it was solid and, so far as appears even now in hindsight, in crucial respects it was overwhelming. In prior arguments regarding his motion for a new trial, Theodore drew attention to Noonan’s admission that he had not looked at CDs provided by the government in discovery that contained a large volume of potentially relevant documents. It is not clear from the record whether the CDs included documents not otherwise viewed in paper form by

³ Noonan had tried unsuccessfully to have the evidence of the plea and colloquy excluded.

Noonan,⁴ but even if they did, Theodore has not now made any substantial proffer that documents that Noonan would have seen if he had viewed the CDs would have significantly weakened the government's case.

III. Theodore's Current Arguments

In his brief in support of his amended motion for a new trial, Theodore argues that Noonan's representation was subpar in three ways that caused him actual prejudice: (1) he failed to stress Theodore's "good faith" belief in his claims about LK-200 and his own standing as a doctor; (2) he failed to contest the materiality of alleged misrepresentations; and (3) he failed to present expert witnesses concerning the patentability of LK-200.⁵

A. "Good Faith"

Proof of mail fraud requires proof of a specific intent to defraud. A defendant's good faith belief in the truth of statements alleged by the government to be false is a defense to mail fraud, because good faith necessarily negates a specific intent to defraud. See United States v. Mueffelman, 470 F.3d 33, 36 (1st Cir. 2006); United States v. Dockray, 943 F.2d 152, 155 (1st Cir. 1991).

1. Patents

At trial, Noonan attempted to question Gary Coulter, who became president of PBC in 1994, about the company's application for a patent related to LK-200. When the government

⁴ As the court of appeals noted, Noonan also testified that he had reviewed boxes of paper documents at the U.S. Attorney's office and "looked at every single cotton-picking piece of paper" made available to him. Theodore, 468 F.3d at 58.

⁵ Theodore also argues that expert witnesses could have testified about whether he had improperly engaged in the practice of medicine, but he concedes that this "point was not significantly developed by the prosecution." (Mem. of Law in Supp. Of Def.'s Am. Mot. For a New Trial 49.) The failure to attack a point "not significantly developed by the prosecution" could not have resulted in actual prejudice.

objected, the court excluded the evidence as not relevant. Noonan argued unsuccessfully that evidence that PBC was pursuing a patent and that Theodore later actually obtained some patents indicated that the company was engaged in “legitimate scientific research.” (Trial Tr., Day 7, 23, Feb. 21, 2001.) Noonan did not expressly frame his argument in terms of “good faith,” although presenting evidence that PBC was engaged in “legitimate” research that could be patented was a way of seeking to demonstrate that Theodore had a good faith belief in the proprietary nature and value of the LK-200 process and product. It is therefore not accurate for Theodore to argue now that Noonan wholly ignored the issue of good faith, although it is true that his efforts could have been more vigorous and informed.

In any event, Theodore’s current argument that additional evidence about patents related to LK-200 and patents later obtained by Theodore would have weakened the government’s case is mere wishful thinking, because the actual evidence he says should have been introduced by Noonan would not have weakened the government’s case at all. First, PBC did not obtain a patent related to LK-200, although it did file a patent application. The application itself is not part of Theodore’s current proffer and it is therefore not possible to know exactly what it claimed. Instead, Theodore points to an October 7, 1994 letter from a patent attorney, Patrea Pabst, to Coulter commenting on the application.⁶ According to the letter, the application asserted forty-two patent claims, including claims for “a method of culturing cells,” two separate “cytokine product[s],” and separately stated methods for treating various diseases or conditions. (Addendum at 64.) It is not possible to tell from the letter whether the “method of culturing cells” described in the application was the method used at the Woburn facility where LK-200

⁶ The letter itself would not have been admissible as substantive evidence because it is hearsay. It might have been admissible as bearing on Theodore’s state of mind if there were evidence that Theodore read it, which there is not.

was generated, nor whether either of the “cytokine product[s]” claimed in the application was LK-200. It is thus not possible to tell whether the letter is even relevant.

Even if possibly relevant in a broad sense, however, the letter is not helpful to Theodore. It gives the attorney’s opinion that “[i]t is fairly predictable that the current claims will be rejected as lacking utility (35 U.S.C. §101), vague and indefinite (35 U.S.C. §112), overbroad (35 U.S.C. §112), lacking novelty over the prior art (35 U.S.C. §102) and obvious in view of the prior art (35 U.S.C. §103).” (Addendum at 66.) That statement, of course, is fully consistent with the government’s position that LK-200 and the process for making it were matters well-known and in the public domain. The letter recommends that the claims be revised, (*id.* at 66, 67), and that “one of the groups of methods of use claims” be pursued in an amended application, (*id.* at 67). Significantly, the letter did not recommend going forward on the claims relating to a “method of culturing cells” or to the “cytokine product[s],” which would be the claims of possible relevance to the issues in the case.

Theodore has also submitted an affidavit by his present counsel stating that he had spoken to Pabst, the patent attorney who authored the 1994 letter, and that she was available to testify that “the claims [in the patent application] could be considered novel” and that “but for PBC going out of business in 1995, the claims were patentable and patents would have been granted on one or more of those submitted.” (Aff. of Counsel in Supp. of Def.’s Am. Mot. for a New Trial ¶¶ 4-6.) The proffer is too general to merit much consideration. It is also consistent with the tenor of the statements in the letter itself that the methods of use claims might be patentable, but not the method of culturing or cytokine products claims.

Theodore further contends that Noonan should have used two patents subsequently issued to him to counter the government’s position that there was nothing proprietary about LK-200 or

the process of producing it. (Addendum at 29-46.) The patents he points to are for methods of treatment using substances completely distinct from LK-200. They show nothing about the patentability of LK-200 or the process of making it. Although Noonan mentioned them only vaguely to Judge Lindsay, he quite properly excluded them as irrelevant.

2. *Theodore's Practice of Medicine*

Theodore's other argument about Noonan's failure to press good faith as an issue pertains to the government's contentions that Theodore was a "phony doctor" who improperly (and misleadingly) referred to himself as an "M.D." or as "Dr. Theodore." This argument lacks merit for two reasons. First, Noonan did present evidence of Theodore's "M.D." degree and he argued that it gave him the right to cite that degree and call himself "Doctor," even if he was not licensed to practice medicine as a clinician. Again, the argument was not couched expressly in terms of "good faith," but the jury had evidence from which it could have concluded that Theodore did not intend to mislead when he made reference to his having obtained an academic medical degree. Of course, the jury also had evidence that Theodore was acting as if he were a licensed clinician, especially with respect to patients in the Bahamian and Mexican clinics, so it could also have properly concluded that he did in fact intend to mislead about his status as a doctor, notwithstanding the fact of his diploma.

Moreover, the government's rhetorical flourish about a "phony doctor" notwithstanding, any deception by Theodore about his status was decidedly collateral to the main thrust of the government's case. Theodore's touting of his medical degree might have added some aura of scientific respectability to his claims about LK-200—like a spoonful of sugar to help the medicine go down—but it was the falsity of the claims about LK-200 that was the nub of the case, and the evidence, against him. It is indisputable on the evidence that Theodore falsely

passed off a commonly known and commercially available supernatant as a proprietary product of a proprietary process that had both therapeutic and economic value. Whether he committed the fraud as a genuine doctor or as a charlatan was merely a matter of atmospherics. There is no reasonable likelihood that if Theodore had been referred to at trial as “Dr. Theodore” rather than “Mr. Theodore” the outcome would have been any different.⁷

B. Materiality of Certain Misrepresentations

Theodore argues that Noonan inadequately challenged the materiality of certain misrepresentations attributed to him by the government. The first pertains to the testimony of Walter Hayhurst. Hayhurst was an early private investor in PBC. At the time of his investment, he was unaware of the fact that Theodore had been convicted of mail fraud in relation to his application for his license to practice medicine and that he had lost his professional license as well. After he learned the truth, Hayhurst did not seek to withdraw his investment but rather remained involved, suggesting that any misrepresentation by Theodore about his professional status was not material to Hayhurst’s decision to invest in PBC.

Theodore may be right that any misrepresentation about his status as a doctor was immaterial to Hayhurst, but his point is itself immaterial to the question raised by the present motion, which is whether there is a reasonable probability that the verdict would have been different if Noonan had made more of the point. As Theodore himself says in his brief:

[T]he issue of defendant’s license revocation and his prior mail fraud conviction was not material to [Hayhurst]. What mattered to him was the science of the product as he had heard it described not so much by the defendant . . . but, more importantly, by Dr. Phillips.

⁷ Indeed, a jury might more readily find specific intent to defraud in a case where the misrepresentation about a matter of science has come from one trained and skilled in the field rather than from one whose technical knowledge might be thought to be suspect.

(Mem. of Law in Supp. of Def.'s Am. Mot. for a New Trial 40–41.) What Dr. Phillips knew about “the science of the product” was, of course, based on what Theodore had told him about it. Central and essential to the scheme to defraud was Theodore’s misrepresentation of “the science of the product,” and the fact of his intentionally false characterization of the product and process as novel, unique, and proprietary was overwhelmingly established by the evidence.

The other argument ostensibly about materiality pertains to Dr. Phillips’ testimony and is really about what Theodore claims was a missed opportunity to impeach Dr. Phillips. Theodore argues that Dr. Phillips’ testimony at trial that it would be improper and unethical to use PBC’s cytokine product in human subjects could have been impeached by a letter Dr. Phillips wrote in early 1993 to Hayhurst, in which Dr. Phillips wrote that it was a “good idea” to “demonstrate initial safety and efficacy in man and use this to justify other studies which will be required to have a drug approved for use.” (Addendum at 62.) As the government points out in its opposition brief, any inconsistency—and thus any impeachment value—was minor at best in the full context of Dr. Phillips’ testimony. For instance, in other correspondence put in evidence by the government that occurred both before and after the letter to Hayhurst, Dr. Phillips expressly noted that the supernatants being supplied by the University of Pennsylvania to PBC were not suitable for use in humans. It is clear that Dr. Phillips knew that at some point PBC intended to conduct clinical trials in human subjects outside the United States. The evidence also disclosed, however, that Dr. Phillips was concerned that, as he put it in the letter Theodore now argues should have been used, “scientific research, especially that involving man, cannot be done in a hurried way.” (*Id.* at 62.) What Dr. Phillips was arguing for was a long-range plan that was carefully delineated. (*Id.* at 62-63.) In short, the potential impeachment value of the letter Theodore now identifies was minimal at best.

Theodore himself seems to recognize this. His brief acknowledges that “the government’s case as presented was very strong and in that context this impeachment evidence would not be significant.” (Mem. of Law in Supp. of Def.’s Am. Mot. for a New Trial 44.) However, he argues that if the impeachment opportunity were to be considered along with the other missed opportunities related to the “good faith” defense, the cumulative effect would be more significant. That might be true if there were any heft to the “good faith” arguments, but, for the reasons discussed above, there is not.

C. Expert Witnesses

Theodore now also faults Noonan’s failure to present experts to explain the significance of his patents and of his actual practical medical experience. In neither case did the omission to offer expert testimony result in actual prejudice to Theodore. If the patent attorney were to testify consistently with the 1994 letter she wrote, and there is no other proffer concerning the substance of her proposed testimony, the testimony would have been that the claims in the original application would likely have been rejected in the first instance as unoriginal and obvious, that amended claims (the precise content of which is not identified) would have to be formulated, and that the promising claims related to methods of use, rather than methods of culturing or specific cytokine products. Such testimony would not have blunted the government’s strong case that Theodore was misrepresenting the proprietary nature of the public domain process and product PBC was actually generating.

As to an expert on the practice of medicine, it is not clear what Theodore now claims such a witness would add. No specific proffer is made. It seems from his brief that the argument is that an expert could have explained that Theodore’s supervision of the clinical injection of LK-200 into patients at the Bahamian clinic was not the unlicensed practice of medicine, as the

government suggested, but rather the activity of a research scientist engaged in product development. Whatever the likely validity of such a proposition, Theodore does not identify any witness who would actually testify to it under oath.

IV. Summary

The Supreme Court in Strickland instructed:

An error by counsel, even if professionally unreasonable, does not warrant setting aside the judgment of a criminal proceeding if the error had no effect on the judgment. . . . Accordingly, any deficiencies in counsel's performance must be prejudicial to the defense in order to constitute ineffective assistance under the Constitution.

466 U.S. at 691-92. Where, as the First Circuit has said is the case here, prejudice to the defense cannot be presumed, a defendant must affirmatively prove prejudice. Id. at 693.

The defendant must show that there is a reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different. A reasonable probability is a probability sufficient to undermine confidence in the outcome.

Id. at 694.

Theodore has not met this standard for showing actual prejudice. After careful review of the trial record, I conclude that even if Noonan had been more thorough and coherent in his trial performance, the outcome of the trial would have been the same. The government's evidence was overwhelming. It showed that PBC manufactured supernatant in a commonly known process in its Woburn "clean room" facility, froze it, and shipped it to clinics in the Bahamas and Mexico, where it was thawed and injected into patients, or in some cases, sent from the Bahamas back into the United States for injection into patients. There was evidence that Theodore was closely involved in the full extent of this activity. From that close involvement, his knowledge of the scheme to defraud and his specific intent to participate in and further that scheme could

easily be inferred. There was further evidence that Theodore falsely represented that part of the manufacturing process for LK-200 occurred in the Bahamas, so that exemption from U.S. regulation could plausibly be claimed, in order to induce both medical experts and investors to support PBC's project. Evidence from personnel in the Bahamian clinic was uncontradicted that the only "processing" of LK-200 that occurred in the Bahamas was thawing it to room temperature by letting it stand in a beaker. There was no question that shipments of LK-200 were made by FedEx from Woburn to other places in the United States that constituted the specific mailings essential to each of the mail fraud counts.

The regulatory violations charged in counts ten through twelve were also proved by essentially uncontradicted evidence. Neither the Woburn facility (count ten) nor the shipments of LK-200 (count eleven) were approved by the Secretary of Health and Human Services as required by law. Both employees of PBC working at the Woburn facility and employees of the Bahamian clinic testified that some LK-200 was inadequately packaged so that the seals broke, justifying a conclusion that adulterated LK-200 had been shipped in interstate commerce (count twelve).

As against this formidable accumulation of damning evidence, disputes about whether Theodore could justifiably call himself an "M.D." or "Dr. Theodore," or whether he might have obtained some patents on some inventions other than the supernatant marketed as LK-200, were merely marginal. The trial judge's first hand assessment deserves attention. At the hearing held before Judge Tauro, Judge Lindsay explained why he had denied Theodore's original motion for a new trial:

Because I thought that, notwithstanding the poor performance by Mr. Noonan, and applying the Strickland test, that Mr. Theodore had not suffered prejudice because of the poor performance of his lawyer.

I believe the case against him was very strong. The evidence from the government was consistent and it came from many sources and supported the charges. And I saw nothing that could have been done by Mr. Noonan that would have resulted -- that would have had a -- resulted in a different outcome of the trial.

....

[I]t wouldn't have mattered if Clarence Darrow had defended Mr. Theodore, it would have come out the same way.

(Hr'g Tr., Day 1, 138, June 28, 2004.) After my review of the record and consideration of the parties' briefs and arguments on the motion, I have independently come to the same conclusion as Judge Lindsay.

Because he has not demonstrated actual prejudice as required by the second part of the Strickland test, Theodore's amended motion for a new trial on the ground of ineffective assistance of counsel (dkt. no. 363) is DENIED.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.
United States District Judge